General

Guideline Title

Faecal calprotectin diagnostic tests for inflammatory diseases of the bowel.

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Faecal calprotectin diagnostic tests for inflammatory diseases of the bowel. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Oct. 58 p. (Diagnostics guidance; no. 11).

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Faecal calprotectin testing is recommended as an option to support clinicians with the differential diagnosis of inflammatory bowel disease (IBD) or irritable bowel syndrome (IBS) in adults with recent onset lower gastrointestinal symptoms for whom specialist assessment is being considered, if:

- Cancer is not suspected, having considered the risk factors (for example, age) described in Referral guidelines for suspected cancer

 (National Institute for Health and Care Excellence [NICE] clinical guideline 27), and
- · Appropriate quality assurance processes and locally agreed care pathways are in place for the testing.

Faecal calprotectin testing is recommended as an option to support clinicians with the differential diagnosis of IBD or non-IBD (including IBS) in children with suspected IBD who have been referred for specialist assessment, if:

Appropriate quality assurance processes and locally agreed care pathways are in place for the testing.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Inflammatory bowel disease (IBD)
 - Ulcerative colitis
 - Crohn's disease
- Irritable bowel syndrome (IBS)

Guidel	ine	Cate	วดซ
Ouluci	IIIC '	Carci	gor y

Diagr	neie	
Diagi.	10212	

Evaluation

Technology Assessment

Clinical Specialty

Colon and Rectal Surgery

Family Practice

Gastroenterology

Internal Medicine

Pediatrics

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To examine the clinical effectiveness and cost-effectiveness of faecal calprotectin tests to help differentiate between non-inflammatory disorders such as irritable bowel syndrome (IBS) and inflammatory disorders such as inflammatory bowel disease (IBD) in people presenting with any of the following lower gastrointestinal symptoms for at least 6 weeks: abdominal pain or discomfort, bloating, or change in bowel habit

Target Population

Children and adults presenting with any of the following lower gastrointestinal symptoms for at least 6 weeks: abdominal pain or discomfort, bloating, or change in bowel habit

Interventions and Practices Considered

Faecal calprotectin diagnostic tests

Major Outcomes Considered

- Diagnostic accuracy of faecal calprotectin
- Referral rates
- Numbers of colonoscopies with/without faecal calprotectin testing
- Proportion of colonoscopies with no abnormal findings
- Duration from onset of symptoms to definite diagnosis of inflammatory bowel diseases (IBD) late diagnosis of Crohn's disease
- Adverse events such as complications of colonoscopy
- Quality of life
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an External Assessment Group to perform a systematic literature review and economic evaluation on the technology considered in this diagnostics guidance and prepare a Diagnostics Assessment Report (DAR). The DAR for this guidance was prepared by Warwick Evidence (see the "Availability of Companion Documents" field).

Methods

The inclusion criteria were studies comparing faecal calprotectin as a guide to inflammation of the lower intestine, ideally with histology as the reference test, in newly presenting patients. Exclusion criteria included studies of faecal calprotectin for monitoring activity of inflammatory bowel disease (IBD) or response to treatment in people with known IBD.

Recent systematic reviews were also identified, appraised and summarised.

The databases searched for diagnostic studies included the databases Medline, EMBASE, Cochrane Library and Web of Science from their inception up to March 2013. Also, additional sources of grey literature were searched, the reference lists of relevant articles checked, and experts contacted for unpublished data.

The selection was done in three stages, based on fulfilling each of following criteria.

- a. Were the patients newly diagnosed?
- b. Was an acceptable reference standard used?
- c. Were the appropriate outcomes reported; i.e. were sensitivity and specificity data reported or was it possible to derive a 2x2 table to determine them?

The hierarchy of evidence based on reference tests was:

- 1. Gold standard endoscopy (usually colonoscopy) and histology.
- 2. Endoscopy and results by disease but no mention of histology biopsies presumed to have been done.
- 3. Endoscopy with report that no biopsies done. Camera endoscopy included here
- 4. No endoscopy but diagnosis by imaging methods, for example thickened gut wall on computed tomography (CT).
- 5. Clinical follow-up for 6 months

Studies were grouped according to the conditions being compared, with most weight being given to:

- Studies comparing irritable bowel syndrome (IBS) with IBD
- Studies comparing IBD with all non-IBD conditions

Search Strategy

Calprotectin - Diagnostic Studies and Economics

- Medline (Ovid) (1946 to September 2012)
- EMBASE (Ovid) (1980 to September 2012)
- Cochrane library all sections, Sept 2012
- Web of Science Science Citation Index, Conference Proceedings Citation Index 1980 to September 2012
- Auto-alerts: Ran auto-alerts of the above searches in Medline and EMBASE from September 2012 to March 2013 for studies added subsequent to the initial searches

Cost-effectiveness Searches

Ovid MEDLINE from 1996 to October 2012, EMBASE 1996 to October 2012, and Cochrane Library, Economic Evaluations Database, Issue 4 of 4, Oct 2012 were searched.

See Appendix 2 in the DAR for additional information on search strategy including search terms used.

Other Searches for Calprotectin

- Searched the website of the journal Gut
- Searched ECCO (European Crohn's and Colitis Organisation) 2012 and 2013 Congress abstracts
- Checked reference lists of previous systematic reviews
- · Personal communication with experts for unpublished data

Searches for Adverse Effects of Colonoscopy

Ovid Medline 1946 to February 2013

Natural History/Progression of IBD

Ovid Medline 1946 to October 2012

Research in Progress (included only open studies and excluded studies with unknown status)

- ClinicalTrials.gov
- Current Controlled Trials
- UK Clinical Trials Gateway
- UK Clinical Research Network Study Portfolio
- EU Clinical Trials Register website
- EUDRACT European Clinical Trials Database
- WHO (World Health Organization) Clinical Trials Search Portal

Number of Source Documents

Results of Clinical Effectiveness Review

The database searches retrieved 1273 references and 35 came from additional searches; there were 725 references remaining after de-duplication. All of the 83 full text articles assessed for eligibility were assessed independently by three authors and any differences were resolved by discussion. Twenty-eight studies were included in quantitative synthesis.

Cost-effectiveness

- Seven references were identified in the systematic review of economic analyses.
- The External Assessment Group submitted an economic model.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus (Committee)

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an External Assessment Group to perform a systematic literature review and economic evaluation on the technology considered in this diagnostics guidance and prepare a Diagnostics Assessment Report (DAR). The DAR for this guidance was prepared by Warwick Evidence (see the "Availability of Companion Documents" field).

Methods

Data were extracted from the included studies for 2x2 tables, with faecal calprotectin as screening test and bowel histology as the reference test. If studies fulfilled the other inclusion criteria, but data for 2x2 tables was not available, the External Assessment Group members reported what data were available, such as calprotectin ranges, medians, and interquartile ranges (IQRs), to compare groups with different conditions.

In papers where the numbers of true and false positives and negatives were not reported, but data on sensitivity and specificity and the total numbers of people with and without disease was reported, the data for the 2x2 table were calculated using the Calculator function in RevMan.

Data on five covariates, including faecal calprotectin cut-off level, make of test, age (adult or paediatric), setting (primary or secondary care), and type of test (enzyme-linked immunosorbent assay [ELISA] or point-of-care test [POCT]) were extracted for each study and entered into Review Manager (RevMan).

Statistical Methods

RevMan version 5.2 was used for data entry and analysis to generate forest plots. MedCalc version 12.3.0 for producing statistical data based on the 2x2 tables, including positive likelihood ratio (PLR), negative likelihood ratio (NLR), positive predictive value (PPV), negative predictive value (NPV) and disease prevalence.

Studies that provided sufficient data for calculation of sensitivity, specificity and other diagnostic outcomes were identified, and data was entered into Review Manager version 5.2 for the generation of paired forest plots and receiver operating characteristic (ROC) curves. Further statistical analysis was performed in Stata 12 (StataCorp, 4905 Lakeway Drive, College Station, Texas 77845 USA) to produce likelihood ratios, area under the curve (AUC) and nomograms. The intention was to examine the performance of calprotectin testing over a range of values, starting with the level recommended by the manufacturers, which is most often 50 μ g/g. Where sufficient studies reported results at the same values, the Assessment Group aimed to pool data for each value.

Meta-analysis was performed in accordance with previously reported guidelines for meta-analyses of diagnostic tests using the Stata command Metandi. Pooled estimates for values among different diagnoses were obtained with 95% confidence intervals, assuming a Bivariate model. If there were sufficient studies, The Assessment Group planned to pool data at the same cut-off levels from ELISA and POCT tests separately, and compare them. However only ELISA tests were pooled.

Quality Assessment

Quality assessment of studies was done using items adapted from the QUADAS I tool (in protocol as approved by NICE) (see the DAR for a list

of quality assessment questions used).

The term "quality assessment" is preferred to the more traditional "risk of bias" term because the latter, as used in systematic reviews such as Cochrane ones, is more associated with assessing internal validity of randomised controlled trials. The Assessment Group need to assess external validity through items such a spectrum bias.

All data extractions and quality assessments were done by one author and checked by another.

See Appendix 4 in the DAR for the quality assessment table.

Economics

A review of the cost-effectiveness literature for faecal calprotectin testing was presented. This was followed by a review of studies of quality of life that may be suitable for inclusion in a cost utility analysis of faecal calprotectin testing, health related quality of life for three conditions having to be considered: irritable bowel syndrome (IBS), Crohn's disease and ulcerative colitis. Given the centrality of colonoscopy to the question in hand, a brief review of the adverse events associated with colonoscopy was then presented. A relatively simple cost consequence model of faecal calprotectin testing was then presented, augmented by some considerations around the loss of utility among false negatives during their period of incorrect treatment. This was followed by a full cost utility model, much of the structure of this being drawn from the modelling for CG61:

Diagnosis and management of irritable bowel syndrome in primary care; the modelling for CG152: Crohn's disease: Management in adults, children and young people; and the modelling for the current draft of the ulcerative colitis guideline: Ulcerative colitis: management in adults, children and young people.

Refer to section 3 in the DAR for a full description of the economic evaluation performed by the External Assessment Group.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Developing Recommendations

After reviewing the evidence the Diagnostic Advisory Committee (DAC) agrees draft recommendations on the use of the technology in the National Health Service (NHS) in England. When formulating these recommendations, the Committee has discretion to consider those factors it believes are most appropriate to the evaluation. In doing so, the Committee has regard to any relevant provisions of the National Institute for Health and Care Excellence's (NICE's) Directions, set out by the Secretary of State for Health, and legislation on human rights, discrimination and equality. In undertaking evaluations of healthcare technologies, NICE takes into account the broad balance of clinical benefits and costs, the degree of clinical need of patients under consideration, any guidance issued to the NHS by the Secretary of State that is specifically drawn to the attention of NICE by the Secretary of State, and any guidance issued by the Secretary of State, and the potential for long-term benefits to the NHS of innovation.

The Committee takes into account advice from NICE on the approach it should take to making scientific and social value judgements. Advice on social value judgements is informed in part by the work of NICE's Citizens Council.

The Committee takes into account how its judgements have a bearing on distributive justice or legal requirements in relation to human rights, discrimination and equality. Such characteristics include, but are not confined to: race, gender, disability, religion or belief, sexual orientation, gender reassignment and pregnancy or maternity.

The Committee considers the application of other Board-approved NICE methods policies, such as the supplementary guidance on discounting and the end-of-life criteria, if they are relevant to the evaluation.

Because the Programme often evaluates new technologies that have a thin evidence base, in formulating its recommendations the Committee balances the quality and quantity of evidence with the expected value of the technology to the NHS and the public.

The credibility of the guidance produced by NICE depends on the transparency of the DAC's decision-making process. It is crucial that the DAC's decisions are explained clearly, and that the contributions of registered stakeholders and the views of members of the public are considered. The reasoning behind the Committee's recommendations is explained, with reference to the factors that have been taken into account.

The language and style used in the documents produced by the Committee are governed by the following principles:

- Clarity is essential in explaining how the DAC has come to its conclusions.
- The text of the documents does not need to reiterate all the factual information that can be found in the information published alongside the guidance. This needs careful judgement so that enough information and justification is given in the recommendations to enable the reader to understand what evidence the DAC considered and, if appropriate, who provided that evidence.

The Committee may take into account factors that may provide benefits to the NHS or the population, such as patient convenience. It may also consider costs and other positive or negative impacts on the NHS that may not be captured in the reference-case cost analysis, such as improved processes.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Review of Existing Economic Analyses

Seven references were identified in the systematic review of economic analyses. Although previous economic analyses have typically concluded that faecal calprotectin testing is cost saving compared with diagnostic pathway costs without it, several issues were highlighted in the critique of the literature, which need further consideration. These included: the use of a small sample size to inform the analysis; assumptions about test accuracy and no consideration of false negative results; the analysis considering colonoscopy but not faecal calprotectin testing; studies that were conducted in England but in primary care only; and some studies that were available only in abstract/poster format, which did not allow for a full critique of the analysis.

Cost-effectiveness Model Constructed by the External Assessment Group

Model Aim

Although the scope allowed for the assessment of faecal calprotectin testing for both adults and children in both primary and secondary care, the External Assessment Group modelled 2 specific populations: an adult population in primary care, with faecal calprotectin test accuracies for inflammatory bowel syndrome (IBD) compared with irritable bowel syndrome (IBS), and a paediatric population in secondary care, with faecal calprotectin test accuracies for IBD compared with non-IBD. The External Assessment Group believed these populations reflect the most likely use of faecal calprotectin testing in clinical practice.

The main aim of the model was to assess the impact of faecal calprotectin testing when added to current clinical practice compared with current practice alone on the differentiation of IBD and IBS in primary care. This model was then adjusted to reflect the differing test performances and costs in the paediatric population to provide an approximation of the cost effectiveness of faecal calprotectin testing for distinguishing between IBD and non-IBD. However, the External Assessment Group highlighted the limitation of this approach because the main model structure does not fully account for the non-IBD case mix in the paediatric population (prevalence of IBS in the non-IBD group is lower than that seen in adults).

Base-Case Cost-effectiveness Results - Primary Care

Without faecal calprotectin testing, general practitioner (GP) current practice is highly sensitive in terms of referring people with IBD and is as good as, if not better, than faecal calprotectin testing. Of the 6.3% of people with IBD in the total population, all were identified by the GP current practice strategy and the point-of-care test (POCT) CalDetect strategy. Colonoscopy would correctly identify 6.0% of the 6.3% referred as patients with true positive results (because of its 95% sensitivity), resulting in a total of 0.3% of patients with false negative results. Enzyme-linked immunosorbent assay (ELISA) testing is slightly worse, identifying 5.9% of the 6.3% (because of its lower sensitivity when compared with current practice and the POCT), with 0.4% of patients being classified as having false negative results. Of the 5.9% referred for colonoscopy, 5.6% of patients would be identified as having true positive results, with 0.3% being classified as having false negative results, resulting in a total of 0.7% of patients with false negative results. Therefore, a slightly larger number of people will have IBD but will be incorrectly diagnosed as having IBS when using an ELISA testing strategy when compared with current practice strategy and a POCT CalDetect strategy (0.7% compared with 0.3%).

Within the total patient population, GP current practice incorrectly identified 19.8% of patients as having false positive results (people thought to have IBD but who actually have IBS) and requiring referral for colonoscopy. The rates of patients with false positive results incorrectly referred for

colonoscopy for POCT CalDetect and ELISA were much lower, at 5.1% and 5.6% respectively. Therefore, without faecal calprotectin testing, many of the patients with false positive results would go on to have a colonoscopy, which has a risk (although low) of serious complications such as perforation. Such events are too rare to significantly affect costs, but they do have some quality-adjusted life year (QALY) impact. This is also true for the more common minor adverse effects of colonoscopy (which were not explicitly considered in the model because of a lack of data).

See Table 3 in the original guideline document for base-case per patient costs and QALYs in primary care.

The faecal calprotectin tests were estimated to result in similar average cost savings compared with GP current practice: £83 for the POCT CalDetect and £82 for ELISA per patient. This was mainly because of the lower number of referrals and colonoscopies for false positive results. Average QALY gains of around 0.0007 QALYs were also accrued, although these were limited because the low prevalence of IBD and the similar high sensitivities of the tests resulted in relatively few false negative results. Therefore, the faecal calprotectin testing strategies dominated current practice (provided greater benefit at reduced cost). Some of the QALY differences accrued were from the very slightly lower mortality associated with the lower number of colonoscopies. The POCT CalDetect and ELISA strategies were estimated to be broadly equivalent in terms of costs and QALYs, with only minor differences between them.

Base-Case Cost-effectiveness Results – Secondary Care

The base-case prevalence of IBD of 47.9% increased the importance of test sensitivities compared with the primary care setting, and so the effect of false negative results on the modelling outputs. Within the total patient population, ELISA with the $50 \,\mu\text{g/g}$ cut-off led to 47.4% of patients with true positive results being referred for colonoscopy, while ELISA with the $100 \,\mu\text{g/g}$ cut-off led to 45.0% of patients with true positive results being referred for colonoscopy. Colonoscopy was assumed to have a sensitivity of 95%. So, if all (47.9%) patients were referred immediately for colonoscopy, 45.5% would be diagnosed with IBD. With ELISA with the $50 \,\text{micrograms/g}$ cut-off, 45.0% of the 47.4% of patients referred for colonoscopy were diagnosed as having IBD, while 42.8% of the 45.0% of patients referred for colonoscopy after ELISA with the $100 \,\mu\text{g/g}$ cut-off were diagnosed as having IBD; a net difference between the cut-offs of 2.2%.

Despite the higher IBD prevalence in the secondary care population, the main test differences still lay in the number of unnecessary colonoscopies. Without faecal calprotectin testing, all 52.1% of patients without IBD received a colonoscopy, compared with 13.5% for ELISA with the $50~\mu\text{g/g}$ cut-off and only 9.4% for ELISA with the $100~\mu\text{g/g}$ cut-off.

See Table 5 in the original guideline document for the base-case per patient costs and QALYs in secondary care.

Prior testing using ELISA was estimated to dominate (provided greater benefit at reduced cost) the strategy of sending all patients directly for colonoscopy. Compared with referring all patients directly for colonoscopy, ELISA used at the 50 μ g/g cut-off was estimated to save £205 per patient, while ELISA used at the 100 μ g/g cut-off was estimated to save £240 per patient. QALY gains of around 0.001 QALYs were estimated for ELISA compared with direct referral for colonoscopy, these being slightly larger for ELISA with the 50 μ g/g cut-off because of its better sensitivity. The additional average cost of £35 and additional average QALYs of 0.0001 for ELISA with the 50 μ g/g cut-off compared with ELISA with the 100 μ g/g cut-off resulted in an incremental cost-effectiveness ratio (ICER) of £35,000 per QALY gained.

See Sections 5 and 6 in the original guideline document for additional information.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

The National Institute for Health and Care Excellence (NICE) sends the Diagnostics Assessment Report (DAR), with any confidential material removed, to registered stakeholders for comment. Stakeholders have 10 working days to return comments. Models supporting the DAR are made available to registered stakeholders on request during this period.

NICE presents anonymised registered stakeholder comments on the DAR, along with any responses from NICE or the External Assessment Group (EAG), to the Committee and later publishes these comments on its website.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The Diagnostics Advisory Committee considered clinical and cost-effectiveness evidence from a systematic review and economic evaluation of faecal calprotectin diagnostics tests prepared by an External Review Group.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of faecal calprotectin diagnostic tests to differentiate between non-inflammatory disorders such as irritable bowel syndrome (IBS) and inflammatory disorders such as inflammatory bowel disease (IBD)

Potential Harms

False-positive and false-negative results of diagnostic tests leading to adverse health comes and increased costs, including the adverse impacts of unnecessary colonoscopies

Qualifying Statements

Qualifying Statements

- This guidance represents the view of the National Institute for Health and Care Excellence (NICE) and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Implementation of the Guideline

Description of Implementation Strategy

•	The National Institute for Health and Care Excellence (NICE) has developed tools (see also the "Availability of	
	Companion Documents" field) to help organisations put this guidance into practice. This may include adoption support work from the NICE	
	Health Technologies Adoption Programme	
NICE will support this guidance with a range of activities to promote the recommendations for further research. This will include		
incorporating the research recommendations in section 7 of the original guideline document into the NICE guidance research		
	recommendations database (available on the NICE website) and highlighting these recommendations to public	
	research bodies. The research proposed will also be put forward to NICE's Medical Technologies Evaluation Programme research	
	facilitation team for consideration of the development of specific research protocols.	

Implementation Tools

Mobile Device Resources

Resources

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Faecal calprotectin diagnostic tests for inflammatory diseases of the bowel. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Oct. 58 p. (Diagnostics guidance; no. 11).

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2013 Oct

Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

Guideline Committee

Diagnostics Advisory Committee

Composition of Group That Authored the Guideline

Standing Committee Members: Professor Ron Akehurst, Professor in Health Economics, School of Health & Related Research, University of Sheffield; Dr Trevor Cole, Consultant Clinical and Cancer Geneticist, Birmingham Women's Hospital; Professor Paul Collinson, Consultant Chemical Pathologist & Professor of Cardiovascular Biomarkers, St George's Hospital; Dr Sue Crawford, General Practitioner (GP) Principal, Chillington Health Centre; Professor Ian A Cree, Senior Clinical Advisor, NIHR Evaluation Trials and Studies Coordinating Centre, University of Southampton; Professor Erika Denton, National Clinical Director for Diagnostics, NHS England, Honorary Professor of Radiology, University of East Anglia and Norfolk and Norwich University Hospital; Dr Simon Fleming, Consultant in Clinical Biochemistry and Metabolic Medicine, Royal Cornwall Hospital; Professor Chris Hyde, Professor of Public Health and Clinical Epidemiology, Peninsula Technology Assessment Group (PenTAG); Professor Noor Kalsheker, Professor of Clinical Chemistry, University of Nottingham, Dr Mark Kroese (Vice Chair), Consultant in Public Health Medicine, PHG Foundation, Cambridge and UK Genetic Testing Network; Professor Adrian Newland (Chair); Dr Richard Nicholas, Consultant Neurologist, Honorary Senior Lecturer, Heatherwood and Wexham Park Hospitals; Mr Stuart Saw, Director of Finance, North East London and the City PCTs; Professor Mark Sculpher, Professor of Health Economics at the Centre for Health Economics, University of York; Dr Steve Thomas, Consultant Vascular and Cardiac Radiologist at Sheffield Teaching Hospitals Foundation Trust; Mr Paul Weinberger, CEO, Diasolve Ltd, London; Mr Christopher Wiltsher, Lay member; Mr David Evans, Lay member; Dr Gail Norbury, Consultant Clinical Scientist, Guy's & St Thomas' NHS Foundation Trust; Dr Peter Naylor, Chair/General Practitioner, Wirral Health Commissioning Consortium; Dr Steve Edwards, Head of Health Technology Assessment, BMJ Evidence Centre

Specialist Committee Members: Dr Anjan Dhar, Senior Lecturer in Gastroenterology, Consultant Gastroenterologist, Darlington Memorial & Bishop Auckland Hospitals; Dr John O'Malley, Organisational Medical Director/GP, Mastercall Healthcare; Mr Nick Read, Lay member; Dr Raian Sheikh, General Practitioner, Orchard Medical Practice; Dr Simon Whitehead, Trainee Clinical Scientist, New Cross Hospital; Dr Robert Logan, Consultant Physician & Gastroenterologist, King's College Hospital NHS Foundation Trust

Financial Disclosures/Conflicts of Interest

Committee members are required to submit a declaration of interests on appointment, in every year of their tenure, and at each Committee meeting, in line with the National Institute for Health and Care Excellence's (NICE's) code of practice for declaring and dealing with conflicts of interest.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the National Institute for Health and	l Care Excellence (NICE) Web	site	. Also available
for download as a Kindle or EPUB ebook from the NICE Web site			

Availability of Companion Documents

The following are available:

- Waugh N, Cummins E, Royle P, Kandala N-B, Shyangdan D, Arasaradnam R, Clar C, Johnston R. Faecal calprotectin testing for
 differentiating amongst inflammatory and non-inflammatory bowel diseases: a systematic review and economic evaluation. Diagnostics
 assessment report. Warwick (UK): Warwick Evidence, Warwick Medical School; 2013 Apr. 244 p. Electronic copies: Available from the
 National Institute for Health and Care Excellence (NICE) Web site
- Waugh N, Cummins E, Royle P, Kandala N-B, Shyangdan D, Arasaradnam R, Clar C, Johnston R. Faecal calprotectin testing for
 differentiating amongst inflammatory and non-inflammatory bowel diseases: a systematic review and economic evaluation. Diagnostics
 assessment report addendum. Warwick (UK): Warwick Evidence, Warwick Medical School; 2013 Apr. 12 p. Electronic copies: Available
 from the NICE Web site
- Faecal calprotectin diagnostic tests for inflammatory diseases of the bowel. Costing template. London (UK): National Institute for Health

	and Care Excellence (NICE); 2013 Oct. (Diagnostics guidance; no. 11). Electronic copies: Available from the NICE Web site
•	Diagnostics Assessment Programme manual. London (UK): National Institute for Health and Care Excellence; 2011 Dec. 130 p. Electronic
	copies: Available from the NICE Web site

Patient Resources

The following is available:

• Faecal calprotectin diagnostic tests for inflammatory diseases of the bowel: information for the public. National Institute for Health and Care Excellence (NICE); 2013 Oct. (Diagnostics guidance; no. 11). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on December 31, 2014.

The National Institute for Health and Care Excellence (NICE) has granted the National Guideline Clearinghouse (NGC) permission to include summaries of their Diagnostics guidance with the intention of disseminating and facilitating the implementation of that guidance. NICE has not verified this content to confirm that it accurately reflects the original NICE guidance and therefore no guarantees are given by NICE in this regard. All NICE diagnostics guidance is prepared in relation to the National Health Service in England and Wales. NICE has not been involved in the development or adaptation of NICE guidance for use in any other country. The full versions of all NICE guidance can be found at www.nice.org.uk

Copyright Statement

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

Disclaimer

NGC Disclaimer

The National Guideline Clearinghouseâ, & (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.